August 25, 2020

Gangan Medical Technology Jiangsu Co., Ltd.
% Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd.
R912, Building #15, XiYueHui, No.5, YiHe North Rd., FangShan District
BeiJing, China 102401

Re: K192464
Trade/Device Name: Injection Pen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: July 21, 2020
Received: July 23, 2020

Dear Ray Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For CAPT Alan Stevens
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

K192464 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

1. **Date of Preparation**: August 12, 2020

2. **Sponsor Identification/Contact Information:**

Submitter Name: Gangan Medical Technology Jiangsu Co., Ltd.
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3. **Identification of Subject Device**

510(k) Number: K192464
Trade Name: Injection Pen Needle
Common Name: Hypodermic single lumen needle
Classification Name: Needle, hypodermic, single lumen
Regulatory Classification: 2
Product Code: FMI
Regulation Number: 21 CFR 880.5570
Review Panel: General Hospital;

4. **Identification of Predicate Device(s)**

510(k) Number: K171982
Product Name: Droplet Pen Needles
Common Name: Hypodermic single lumen needle
Classification Name: Needle, hypodermic, single lumen
Regulatory Classification: 2
Product Code: FMI
Regulation Number: 880.5570
Review Panel: General Hospital

5. **Indications for Use Statement:**

The Injection Pen Needle is intended for use with pen injector devices for the subcutaneous injection of drugs.

6. **Device Description**

The Injection Pen Needle is designed for use with pen injectors for subcutaneous injection of a desired dose

of drugs approved for delivery using a pen needle. It consists of a seal, needle hub, needle tube, needle sheath and primary container. The Injection Pen Needle is offered in the following sizes: Model(s): 0.30x6mm/30G, 0.30x8mm/30G, 0.25x6mm/31G, 0.25x8mm/31G, 0.23x4mm/32G

It is a single-use disposable device that is provided sterile and has a shelf life of 3 years. The needle hub is connects to the pen injector and the needle tube punctures the sealed medicine container. The medicine solution is pushed out through the needle tube by the injection mechanism of the pen injector.

The needle tube is a stainless steel needle tube with lubricant coating on the surface and a beveled tip. The seal (medical glue-coated dialysis paper) and the primary container (medical polypropylene) constitute the sterile barrier system of the product.

7. Comparison of Technology to Predicate Device

A technological comparison table is provided below that compares the subject device and predicate device:

Table 1 Comparison Table

Item	Proposed Device(s)	Predicate Device(K171982)	Remark
Device name	Injection Pen Needle	Droplet Pen Needle	N/A
Classification Name	Needle, hypodermic, single lumen	Needle, hypodermic, single lumen	SAME
Product Code	FMI	FMI	SAME
Regulation Number	21 CFR 880.5570	21 CFR 880.5570	SAME
Intended Use	The Injection Pen Needle is intended for use with a pen injector device for the subcutaneous injection of drugs.	The Droplet® Pen Needle is intended for use with a pen injector device for the subcutaneous injection of drugs.	SAME
Prescription/OTC	Prescription Use	Prescription Use	SAME
Components	Primary Container, Needle Sheath, Needle Tube and Hub	Primary Container, Needle Shield, Needle Tube and Hub	SAME
Supplied Sterile	Yes	Yes	SAME
Single use	Yes	Yes	SAME
Principle of operation	Manual	Manual	SAME
Compatibility	Pen Injector Device	Pen Injector Device	SAME
Method of attachment to pen injector	Screw threads	Screw threads	SAME
Length	4mm, 6mm, 8mm	4mm, 5mm, 6mm, 8mm, 10mm, 12mm	SAME
Gage	30G, 31G, 32G	29G, 31G, 32G	Different
Sterilization Method	EO	Gamma irradiation	Different
Sterility	SAL=10^{-6}	SAL=10^{-6}	SAME
Shelf Life	3 years	5 years	Different
Unit Packaging	Polypropylene container with seal made of medical grade	Polypropylene container with seal made of medical grade	SAME

		paper	paper	
Materials	Needle Tube	304 austenitic stainless steel	Medical Grade Stainless Steel	Similar
	Hub, Primary Container, Needle Sheath	Polypropylene	Polypropylene	Similar
	Lubricant	Medical grade silicone	Medical grade silicone	Similar
	Adhesive	UV Cured Adhesive	Not Available	Different
Performance Compliance		ISO 11608-2, ISO 9626, ISO 7864	ISO 11608-2, ISO 9626, ISO 7864	SAME
Biocompatibility		Biocompatibility evaluation per ISO 10993-1	Biocompatibility evaluation per ISO 10993-1	SAME

The indications for use and intended use of the subject device is equivalent to that of the predicate device. The differences that exist between the subject device and predicate device are the following:

- Gauge size
- Shelf life
- Sterilization method
- Materials of composition

Based on the aforementioned modifications to the subject device, the subject device does not raise different types of safety and effectiveness questions when compared to the predicate device. Differences between the devices were verified or validated through non-clinical testing.

8. Non-Clinical Test Summary

Non clinical tests were conducted to verify that the Injection Pen Needle met all design specifications and is Substantially Equivalent (SE) to the predicate device. Testing was conducted in accordance with recognized standards and FDA Guidance.

Performance**:**

The Injection Pen Needle was tested for device performance in accordance with the following recognized standards. Results of the testing demonstrated that the acceptance criteria were met for all gauges and lengths of needles and would support a shelf life of 3 years.

- ISO 7864:2016 Sterile hypodermic needles for single use - Requirements and test methods.
- ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices -Requirements and test methods.
- ISO 11608-2:2012 Needle-based injection systems for medical use - Requirements and test methods - Part 2: Needles.

Compatibly was demonstrated to the following FDA cleared/approved injectors via ISO 11608-2: 2012 clauses 4.4 and 4.9: PEN INJECTOR - HumaPen Luxura (K142518); PEN INJECTOR - NovoPen Echo (K182387); PEN INJECTOR - NOVOLOG MIX 70/30 (BLA 021172); PEN INJECTOR - LANTUS SOLOSTAR (BLA 021081).

Biocompatibility:

The Injection Pen Needle was evaluated for biocompatibility endpoints associated with a limited contact (≤ 24 hrs) external communicating, circulating blood contacting device per FDA Guidance: "Use of International Standard ISO 10993-1. Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process, June 2016" and the list of recognized standards below. The endpoints evaluated include: Cyotoxicity, Sensitization, Irritation, Acute Systemic Toxicity, Hemocompatibility, Pyrogenicity. Results of the testing demonstrated that the acceptance criteria were met.

- ISO 10993-5:2009, Biological Evaluation of Medical Device, Part 5-Tests for Vitro cytotoxicity.
- ISO 10993-10:2010 Standard, Biological Evaluation of Medical Device, Part 10-Test for irritation and delay-type hypersensitivity.
- ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.
- ISO 10993-4:2017 Biological evaluation of medical devices--Part 4: Selection of tests for interactions with blood.
- ASTM F756, Standard Practice for Assessment of Hemolytic Properties of Materials
- USP41 <85> Bacterial Endotoxins Test.

Sterility

The Injection Pen Needle is supplied sterile in sterile packaging for single use and is sterilized by Ethylene Oxide to achieve a SAL of 10^{-6} . Sterilization was validated and tested to ensure that sterility is maintained during the shelf life of 3 years in accordance with the following recognized standards. Results of the testing demonstrated that the acceptance criteria were met.

- ISO 11135:2014 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
- ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
- ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

9. Substantially Equivalent Conclusion

Differences between the technological characteristics of the subject device as compared to the predicate do not raise different questions of safety and effectiveness. The differences between the device are supported by non-clinical testing. The Injection Pen needle is Substantially Equivalent (SE) to the Droplet Pen Needles, cleared under K171982.